EXPORT MARKETS DEVELOPING A PENCHANT FOR ACCURACY

by Mark Bello,
Office of Public and Business Affairs, National Institute of Standards and Technology

Measurements are the common language of global commerce. They are used to specify product features and performance, to characterize processes and to assess compliance with regulations. But the words of this technical discourse can become jumbled and hollow if they are not backed by reliable sources—internationally recognized measurement references.

Suppliers, for example, may assert that their parts or products meet specifications. But can customers be confident that measurements underlying these claims are accurate? And how can suppliers demonstrate the validity and reliability of their measurement results to skeptical buyers or regulators?

The validity of measurements is easily challenged by a deceptively simple question: "Compared to what?" Measurements that are beyond compare might inspire an offbeat poet, but they can be dismissed by customers and regulators. In contrast, measurements that are compared to accepted international or national standards inspire the confidence of trading partners.

Increasingly, exporters are being required to demonstrate that their measurement results, as realized in product specifications and tolerances, are "traceable" to recognized standards. In response, the Commerce Department's National Institute of Standards and Technology—the premier measurement laboratory in the United States—has created a new web site (www.nist.gov/traceability/) to provide traceability novices and veterans with key information on this increasingly important topic.

UNBROKEN CHAIN

"More and more of our customers are asking questions about traceability," explains NIST Acting Director Karen Brown. "These range from the most basic—What is it?—to the more complex—How can I judge the credibility of suppliers' claims that their measurements are linked to those developed and maintained by NIST and ultimately to the SI, the International System of Units?"

Claims of accuracy can be judged on the basis of a kind of pedigree, a well documented and continuous line of measurement comparisons—each with an established level of uncertainty. In effect, this unbroken chain of comparisons transfers accuracy—link by link—to the manufacturing floor, clinic or anywhere else that reliable measurements matter.

The chain typically begins with state-of-the-art, high-accuracy measurement references and services supplied by NIST or a counterpart national measurement laboratory in another country. Testing laboratories, makers of high-precision instruments and regulatory agencies are among the types of organizations that calibrate their measurement equipment directly against NIST references.

Most organizations have less demanding measurement needs, however. They can tolerate the additional—and accumulating—uncertainty that is introduced with each successive comparison along the chain. To demonstrate traceability, they can calibrate equipment against intermediate or lower-tier references that may be several interconnected links away from the highest-order standard available from NIST or another accepted authority.

Except for defense suppliers and heavily regulated U.S. industries, such as utilities and pharmaceuticals, formal measurement traceability requirements have been relatively rare. For the most part, measurement-intensive sectors established their own systems for assessing accuracy and ensuring high levels of quality control.

MORE SYSTEMATIC APPROACH

The 21st century marketplace appears to be moving toward more formalized and more systematic approaches for ensuring—and demonstrating—measurement accuracy. Major impetus for this transition has come from quality

management system standards issued by the International Organization for Standardization, or ISO. Adopted by more than 350,000 organizations in 150 nations, the so-called ISO 9000 family of standards specifies that, when possible, measuring equipment should be calibrated against standards traceable to international or national measurement standards.

Since many large manufacturers require their regular suppliers to be ISO 9000 registered, a growing legion of businesses is becoming familiar with measurement traceability.

Another ISO Standard—the recently approved standard in the "geometrical product specifications" series (ISO 14523: Part 1)—deals with rules for deciding whether a part meets specifications. It obliges suppliers and purchasers of parts to quantify the uncertainty of their dimensional and geometric measurements, necessitating traceability to higher-order standards. It also requires suppliers to subtract their measurement uncertainty from the tolerance.

"This could cause some trouble in industries, such as advanced optics, where they are making parts close to the limits of measurement technology," says NIST precision engineering expert Chris Evans. "Unless suppliers make contractual arrangements to the contrary, parts may be required, by default, to comply with the standard, leaving little room for manufacturing variation."

Also, the European Union will require makers of in vitro diagnostic test systems (IVD products) to demonstrate, by 2003, traceability to "reference materials of a higher order." Vendors will have the option of establishing independently the accuracy of their measurement results. Yet, observers suggest that alternatives to formal traceability may prove to be more difficult and ultimately may complicate efforts to secure the CE mark for IVD products.

These developments and others—including a proliferation of regulations in some sectors—are making traceability a matter of interest for more than measurement professionals.

At NIST's traceability web site, a heavy stream of visitors is already exploring the ins and outs of this systematic approach to demonstrating accuracy. There, they can learn about NIST's calibration services and its more than 1,300 different Standard Reference Materials—benchmark references for measurements of everything from the carbon content of steel to cholesterol levels and from temperature to the diameter of optical fiber. Visitors can read the NIST policy on traceability. They also can review easy-to-understand answers to an extensive set of "frequently asked questions" about traceability, from the most general to specific points about laboratory accreditation. Other resources include a glossary of terms and a traceability checklist for users of calibration services.

GLOBAL ACCEPTANCE SOUGHT

"Businesses know the level of accuracy they must achieve in product and process measurements," explains Richard Kayser, NIST's director of Technology Services. "To satisfy traceability requirements they will have to make certain that each step they take to reach this level can be related back to national or international standards. And they must know how to support their claims of measurement traceability. Just as important, they must be able to evaluate traceability claims made by suppliers and by providers of measurement services."

But NIST and its counterparts must go beyond supporting traceability within their borders. "We should enable global acceptance of measurement results traceable to individual National Metrology Institutes (NMIs), be it NIST in the United States, the Physikalisch-Technische Bundesanstalt in Germany or the National Metrology Laboratory in South Africa," says Robert Watters, manager of a NIST program focused on this objective.

"We need comparability and harmonization of measurement results across national borders," he explains. "Otherwise, we will not make any progress in reducing redundant testing that can impede access to export markets."

Now, for example, a regulator or a customer in a foreign market may only recognize measurement results that are traceable to a particular NMI. This may necessitate testing U.S.-made products at a foreign laboratory, duplicating testing already done in the United States.

YOUR NMI OR MINE

Watters and his collaborators are building the machinery to establish the equivalence of measurement results on regional and, ultimately, global scales. NIST has set up the International Comparisons Database, a vehicle for comparing the measurement and calibration capabilities of NMIs around the world, with special emphasis on the Western Hemisphere. With the database, a Brazilian purchaser of electrical equipment manufactured in the United States could determine that power and voltage measurements shown to be traceable to NIST are equivalent to those traceable to INMETRO, Brazil's NMI.

The database supporting the so-called Inter-American Metrology System also contains data from other NMIs, as supplied by a comparison and calibration database maintained by the International Bureau of Weights and Measures, a treaty organization that has the task of ensuring worldwide unification of physical measurements. With links to all of the world's regional metrology organizations, this organization's database will eventually provide direct and indirect means to judge the degree of equivalence of measurement capabilities in different countries, which could ease the burdens retesting.

"The databases should open the door to achieving traceability by alternative routes," Watters says. "Our aim is to move the database from the exclusive realm of the measurement scientist and make it an easy-to-use tool for companies and regulators, providing them with a clear line of sight for assessing the degree of equivalence of measurement results. Ultimately, our hope is that this tool will help to eliminate technical barriers to market entry."

To learn more about the International Comparisons Database visit the program's web site at: http://icdb.nist.gov/.

TRACEABILITY IN THE CLINIC

Traceability provides a way of relating the results of a measurement to higher-level standards, helping to ensure consistency and reliability. In the United States, traceability systems are well established in the radiopharmaceutical industry.

About 37,000 nuclear medicine procedures are performed daily in U.S. hospitals and clinics. Used mainly in the diagnosis of cancer, cardiovascular disease and neurological disorders, radioactively labeled drugs must be administered in exceedingly accurate doses. The aim is to limit radiation exposure to the level needed to capture essential information on the patient's condition. In addition to diagnostic procedures, more than 100,000 therapeutic nuclear medicine procedures are performed annually. The primary example is the treatment of thyroid cancer patients with iodine-131, but new radiopharmaceutical therapies are emerging. Here, too, the accuracy of dosage is key. Accuracy in the administration of radiopharmaceuticals to patients depends on the accuracy of measurement instruments used in the manufacturing process. These instruments are traceable to NIST primary standards for radioactivity. Organizations involved in establishing this traceability system include the pharmaceutical manufacturers of North America, under the auspices of the Nuclear Energy Institute, the U.S. Food and Drug Administration, the NIST Physics Laboratory and the NIST Standard Reference Materials Program.

WEB SITES OF INTEREST

Traceability: NIST Policy and Supplementary Materials: www.nist.gov/traceability/
Features include answers to frequently asked questions, calibration checklist and more.

Reference on constants, measurement units and uncertainty: physics.nist.gov/cuu/
Offers information and guidance on expressing measurement uncertainty—a key element of traceability—as well as useful background material on the international measurement system.

NIST International Comparisons Database: http://icdb.nist.gov/
Developing resource for comparing the capabilities, measurements and measurement standards of "national metrology institutes," especially those in the Western Hemisphere. Links to the Key Comparison and Calibration Database of the International Bureau of Weights and Measures.

NIST Standard Reference Materials Program: http://ts.nist.gov/srm
NIST offers about 1,300 different types of measurement standards to support industrial, environmental, health and science applications.

NIST Calibration Services: http://ts.nist.gov/calibrations
Features detailed listing of types of instrument calibrations and special tests that NIST performs in support of makers and users of high-precision equipment.

Conformity Assessment: http://ts.nist.gov/ca
Provides "one-stop shopping" for background information on conformity assessment—the various and sometimes confusing procedures used to assess whether products or services comply with requirements.